DRAFT

Question 4

A number of separate pieces of information are needed to make the assertion that a specific type of cigarette is less harmful than others (see Figure 1). The process would include standard acceptability testing which would involve smoke chemistry and both *in vitro* and *in vivo* toxicology testing. Once the product is on the market definitive exposure assessment could be made. Due to the need for large numbers of smokers who currently use a product as their brand it would best to conduct this study in an after-market environment. (See the response to question 7 for more information about exposure measurement, including biomarkers of exposure.) By combining the information from the exposure assessment and the acceptability testing it may be possible to make a provisional claim or assertion about the product as having reduced-risk characteristics. It may be that additional testing relevant to a specific health endpoint is needed before such a claim is made. This testing would be conducted in animals or cell culture systems and would be directed toward specific health endpoints not extensively evaluated in the standard acceptability test battery. (Please see the response to question 6 for more information about these tests). Of course this testing could be conducted prior to introduction into the marketplace; but would not need to be done at that time. At this point any claim or assertion about the risk of the product would need to be qualified in a way that expresses the potential for harm reduction but be limited in that no evidence of health benefit in humans has been determined yet. A further step toward the assertion that a particular type of cigarette is less harmful would be the assessment of short-term (after 1 year or less of use) health effects in people. This testing would typically be conducted to assess the potential for changes in long-term (following 10 years or more of use) effects. We have not yet determined the appropriate biomarkers of effect for the various chronic diseases associated with smoking. At this stage an expanded claim or assertion could be made. However, even this assertion would need to have some limitations. Following the completion of long-term studies in people a definitive claim could be made. Due to the long time needed to reach this level of claim it would be critical to provide earlier guidance to consumers using the information discussed above.

- i.e. no Risk harm

analysed

The claims made at any of these stages should be made based on well-designed studies with results that are statistically significant and biologically relevant. The endpoints measured must have a clear link to the human health effect of interest.

do any?

PM3006856750

Source: https://www.industrydocuments.ucsf.edu/docs/nplx0001